



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,662	07/15/2003	William Howard Roark	PC25132A	7178
28880	7590	05/10/2006	EXAMINER	
WARNER-LAMBERT COMPANY			OLSON, ERIC	
2800 PLYMOUTH RD				
ANN ARBOR, MI 48105			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/619,662	Applicant(s) ROARK, WILLIAM HOWARD	
	Examiner Eric S. Olson	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>April 8, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is in response to Applicant's amendment and election filed April 20, 2006 wherein claims 1-2 are cancelled and claims 4-9 are amended. Claims 3-9 are pending in this application and examined on the merits herein.

Applicant's election with traverse of the species of claim 3, (Group IV of the previous restriction requirement) is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. (MPEP § 818.03(a)) The requirement for restriction is therefore deemed proper and made FINAL.

Applicant's preliminary amendment submitted April 20, 2006 is acknowledged wherein claims 1-2 are cancelled and claims 4-9 are amended.

Applicant's observation in a communication filed April 20, 2006, of an inconsistency on p. 4 of the previous office action is acknowledged. As suggested by the applicant, the previous office action referred to groups I-VI, not groups I-IX.

Title

The title of the invention is not descriptive. The title mentions celecoxib even though celecoxib is not a component of the claimed invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Combination of an allosteric carboxylic inhibitor of matrix metalloprotease 13 with valdecoxib.

Abstract

The following is a quotation from 37 CFR § 1.72:

(b) A brief abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure." The sheet or sheets presenting the abstract may not include other parts of the application or other material. The abstract in an application filed under 35 U.S.C. 111 may not exceed 150 words in length. The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure.

The abstract of the disclosure is objected to because it exceeds 150 words in length. It is suggested that all references to celecoxib be removed, as celecoxib is not part of the claimed invention. This amendment would reduce the abstract to an allowable length. Correction is required. See MPEP § 608.01(b).

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cartilage damage and arthritis in a mammal, does not reasonably provide enablement for the treatment of all types of pain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention concerns a method of using a pharmaceutical composition comprising valdecoxib and an allosteric inhibitor of matrix metalloprotease 13 of the structure (VG) given in claim 3 for the treatment of a number of diseases, including arthritis, inflammation, cartilage degeneration, and pain.

The state of the prior art: Matrix metalloproteinase 13 is known to be a promising molecular target for anti-arthritis drugs. Its activity in the degradation of the extra-cellular matrix and destruction of cartilage is well known. Valdecoxib is known to be useful as a non-steroidal anti-inflammatory drug useful for the relief of symptoms of arthritis and other diseases characterized by inflammation. MMP-13 inhibitors are not known to be generally useful in the treatment of all kinds of pain or inflammation.

The treatment of pain is a complex art due to the fact that pain can be caused by many different disorders, and no one treatment is universally useful for the treatment of all pain. IN particular, pain is divided into neuropathic and nociceptive categories, representing pain arising from a disorder of the nervous system and pain arising from a

Art Unit: 1623

painful stimulus to the nerves, respectively. As described by Woolf et al. (Reference included with PTO-892) drugs used to treat nociceptive pain, including non-steroidal anti-inflammatory drugs such as valdecoxib, are often ineffective against neuropathic pain, such as that arising from nerve injury or diabetes, and vice versa. (p. 1959, left column, second paragraph) According to Woolf et al., "There is no treatment to prevent the development of neuropathic pain, nor to adequately, predictably, and specifically control established neuropathic pain." (p. 1959, left column, third paragraph)

Valdecoxib, as described in US patent 5985902 (reference cited in PTO-892) is useful in a method for treating inflammation and inflammation-related disorders including pain. (Column 2, line 50 – Column 3, line 12, also Claims 14-21) In this context, pain refers to pain caused by or otherwise associated with inflammation, rather than all kinds of pain in general. No mention is made of valdecoxib or related compounds as being useful for the treatment of neuropathic pain or other kinds of pain not associated with inflammation.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While there exist many drugs for the treatment of pain and inflammation, there is no panacea which is capable of relieving all types of pain. Each individual drug for the treatment of pain must be evaluated on its own merits as to the specific cases in which it is or is not useful.

The Breadth of the claims: Claim 5 includes methods of treating all forms of arthritis, inflammation, cartilage damage, and pain using a combination of valdecoxib

Art Unit: 1623

and a compound of formula VG which is a matrix metalloproteinase 13 inhibitor. No limitations are introduced as to the specific type of inflammation or pain to be treated.

Formula VG includes a large number of compounds which share a core structure with various substituents. These compounds are also additionally limited by the requirement that they possess allosteric inhibitory activity against matrix metalloproteinase 13. However, a variety of substituents are included within the limitations of formula VG, and additional biological activities are expected to vary widely between different compounds of formula VG.

The amount of direction or guidance presented: It is shown in the instant specification that a number of compounds of formula (VG) are allosteric inhibitors of matrix metalloproteinase 13. An assay is provided by which additional allosteric inhibitors of matrix metalloproteinase may be identified. Valdecoxib is already well known for the treatment of inflammation and pain, particularly that arising from arthritis. No protocols for the treatment of neuropathic pain are provided, nor is any method provided by which compounds useful for the treatment of neuropathic pain could be readily identified. No evidence is given which would indicate that MMP-13 inhibitors and COX-2 inhibitors, when combined, possess any special synergistic effects against neuropathic pain.

The presence or absence of working examples: No working examples are provided for the treatment of any disorder in any subject.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the pharmacology of

Art Unit: 1623

matrix metalloprotease inhibitors and the treatment of neuropathic pain. See MPEP 2164.

The quantity of experimentation necessary: In order to treat neuropathic pain using the claimed pharmaceutical composition, a skilled practitioner of the art would undertake to develop a therapeutic regimen without precedent in the current state of the art. As the applicant's disclosure provides no guidance for the treatment of neuropathic pain, or any pain not associated with inflammation, the development of this therapeutic method would be an independent research endeavor which would present significant obstacles, mainly arising from the fact that neither of the drugs included in the claimed combination is known to affect any molecular target involved in neuropathic pain. This process would involve the screening of candidate compounds against relevant molecular targets, optimization of lead activity, and validation of lead compounds using *in vivo* animal models of neuropathic pain. Developing such a therapeutic method without guidance from applicant's disclosure represents an undue experimental burden to one skilled in the art wishing to practice the invention.

Genetech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of precedent for treatment of neuropathic pain using

Art Unit: 1623

MMP-13 inhibitors or COX-2 inhibitors, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of neuropathic pain.

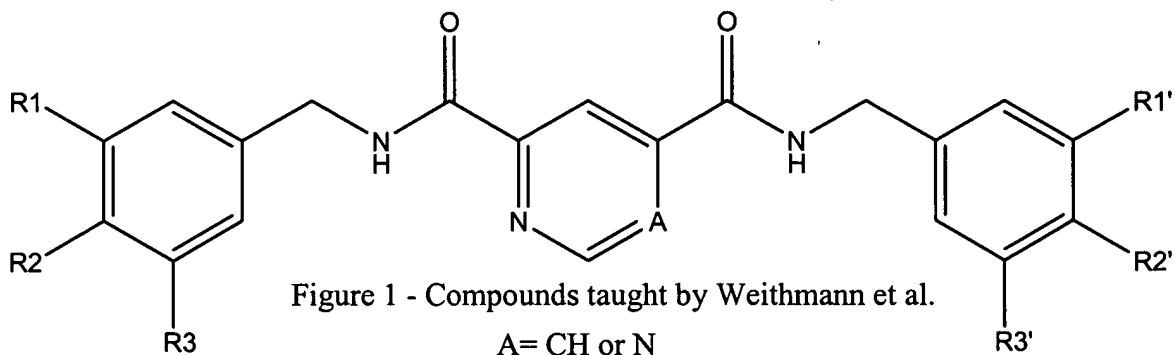
Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weithmann et al. (US patent 6933298, cited in PTO-892) in view of Goldman et. al. (Reference included with PTO-892).

Weithmann et al., which claims benefit of provisional application 60/358897, filed Feb. 22, 2002, teaches a class of compounds of the structure pictured in figure 1 below:



Specific compounds disclosed by Weithmann et al. include examples 4, 7, 8, 9, and 12 of table 1, (columns 11-14) all of which fall within the structural limitations of formula VG of instant claim 3, in which Ar represents a substituted phenyl. Weithmann

Art Unit: 1623

et al. also teaches that the disclosed compounds of figure 1 are selective inhibitors of matrix metalloprotease 13 which are useful for the treatment of degenerative diseases of the joints. (Column 1, lines 18-23) Specific diseases mentioned as being associated with elevated MMP-13 activity, and treatable by the compounds of Weithmann et al., include, "degenerative joint diseases such as osteoartheoses, spondyloses, chondrolysis following joint trauma or a relatively long period of joint immobilization following injuries to the meniscus or patella or the tearing of a ligament. In addition they also include diseases of the connective tissue such as collagenoses, periodontal diseases, wound healing disturbances and chronic diseases of the locomotor system, such as inflammatory, immunologically or metabolism-determined acute and chronic arthritides, arthropathies, myalgias, and disturbances of bone metabolism or cancer diseases such as breast cancer." (column 8, 46-56) Information is also given concerning possible pharmaceutical preparations and dosage units which may be prepared from these compounds. (Column 8 line 62 – Column 9, line 52) Weithmann et al. does not teach a combination of a pyridinedicarboxamide with valdecoxib or any other COX-2 inhibitor.

Goldman et. al. teaches that Valdecoxib is, "A COX-2 Inhibitor for Treatment of Osteoarthritis, Rheumatoid Arthritis, and Primary Dysmenorrhea". (P. 1, title) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teaching of Weithmann et al. by combining valdecoxib with the pyridinedicarboxamide compounds of Weithmann et al.

Art Unit: 1623

One of ordinary skill in the art would have been motivated to combine these two references in this manner in order to treat cartilage damage associated with arthritis (by administering one of the pyridinedicarboxamides of Weithmann et al.) while simultaneously treating pain and inflammation caused by arthritis (by administering valdecoxib). One of ordinary skill in the art would have reasonably expected success because valdecoxib and the compounds of Weithmann et al. were both known to be useful for the treatment of arthritis and were known to act by different mechanisms which could both function simultaneously.

It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 1623

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-9 of copending Application No. 10/620174 ('174, cited in PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention falls entirely within the limitations of claims 1 and 4-9 of '174.

'174 discloses, "A pharmaceutical combination comprising valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof." (Claim 1) Instant claim 3 claims, "A combination comprising valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric carboxylic inhibitor of MMP-13 of formula VG." Thus instant claim 3 is an obvious subspecie of claim 1 of '174.

Claim 4 of '174 claims, "A pharmaceutical composition, comprising a combination of valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier, diluent, or excipient." Instant claim 4 falls entirely within the limits of this claim and is thus an obvious subspecie of claim 4 of '174.

Claims 5-9 of '174. claim various methods of treating diseases comprising administering to an affected mammal, "a therapeutically effective amount of a combination of valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof." The recited diseases are identical to those recited in instant claims 5-9, and the recited class of therapeutic compounds entirely encompasses those recited by instant claims 5-9. The invention of instant claims 5-9 is thus an obvious subspecie of claims 5-9 of '174.

This is a provisional obviousness-type double patenting rejection as the conflicting claims have not in fact been patented.

Claims 3-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-9 of copending Application No. 10/619769 (Cited in PTO-892, herein referred to as '769) in view of Goldman et. al. (Included with PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the claimed invention and the invention of claims 3-9 of '769 involves merely the substitution of one functionally equivalent, well-known prior art compound with another.

Claim 3 of '769 claim combinations of a cox-2 inhibitor other than celecoxib or valdecoxib with an allosteric inhibitor of MMP-13 with the exact same structural limitations as instant claim 3. The claimed MMP-13 inhibitors are not limited by structure and thus fully encompass the MMP-3 inhibitors included in instant claims 3-9. Claims 1-9 of '769 do not claim combinations comprising valdecoxib or any

Art Unit: 1623

pharmaceutical composition or therapeutic method involving such combinations.

However, the specification of said copending application does not provide any reasoning by which valdecoxib alone among all COX-2 inhibitors is unsuitable for combination with an allosteric inhibitor of MMP-13.

Claim 4 of '769 claims a pharmaceutical composition comprising a selective COX-2 inhibitor that is not celecoxib or valdecoxib and an allosteric carboxylic inhibitor of MMP-13. Claims 5-9 of '769 claim therapeutic methods for treating various diseases including cartilage damage, inflammation, arthritis, and pain involving said composition. The MMP-13 inhibitors involved in these claims include inhibitors of formula VG as described in the instant claims 3-9. The list of diseases to be treated is identical to that of instant claims 5-9. However, claims 4-9 of '769 do not include pharmaceutical compositions or therapeutic methods involving valdecoxib as the COX-2 inhibitor.

Goldman et. al. teaches that Valdecoxib is, "A COX-2 Inhibitor for Treatment of Osteoarthritis, Rheumatoid Arthritis, and Primary Dysmenorrhea". (P. 1, title) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of '769 by using valdecoxib as the COX-2 inhibitor in the claimed combinations, compositions, and therapeutic methods instead of using a COX-2 inhibitor other than celecoxib or valdecoxib.

One of ordinary skill in the art would have been motivated to combine the teachings of the two references in order to treat diseases, such as osteoarthritis, that are caused by unbalanced MMP activity, while simultaneously treating the pain and inflammation caused by such conditions. One of ordinary skill in the art would have

Art Unit: 1623

reasonably expected success because '769 already teaches a combination of a COX-2 inhibitor and an allosteric MMP-13 inhibitor, and because valdecoxib was already known to be a therapeutically effective COX-2 inhibitor for the treatment of arthritis and related conditions. The claimed invention of claims 3-9 is an obvious subspecie of this variation of the invention of '769.

This is a provisional obviousness-type double patenting rejection as the conflicting claims have not in fact been patented.

Claims 3-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-9 of copending Application No. 10/619663 (Reference cited in PTO-892, herein referred to as '663) in view of Goldman et. al. (Included with PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention falls entirely within the limitations of claims 1 and 4-9 of '663, with the additional substitution of one functionally equivalent, well-known prior art compound with another.

Claims 1 and 4-9 of '663 claim combinations of a cox-2 inhibitor other than celecoxib or valdecoxib with an allosteric inhibitor of MMP-13, of undefined structure, as well as a pharmaceutical composition and method of treatment of disorders including cartilage damage, inflammation, arthritis, and pain involving said composition. The claimed MMP-13 inhibitors are not limited by structure and thus fully encompass the MMP-3 inhibitors included in instant claims 3-9. The combinations, pharmaceutical compositions, and therapeutic methods that are claimed are identical to those of instant

Art Unit: 1623

claims 3-9 except that the MMP-13 inhibitors included may be of any structure and the COX-2 inhibitor must be a compound other than celecoxib or valdecoxib. Claims 1 and 4-9 of '663 do not claim combinations comprising valdecoxib or any pharmaceutical composition or therapeutic method involving such combinations. However, the specification of said copending application does not provide any reasoning by which valdecoxib alone among all COX-2 inhibitors is unsuitable for combination with an allosteric inhibitor of MMP-13. In fact, paragraph 0006 of '663 specifically describes valdecoxib as being significantly safer than conventional NSAIDs for use in the treatment of arthritis.

Goldman et. al. teaches that Valdecoxib is, "A COX-2 Inhibitor for Treatment of Osteoarthritis, Rheumatoid Arthritis, and Primary Dysmenorrhea". (P. 1, title) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teaching of '663 by using valdecoxib as the COX-2 inhibitor in the claimed combinations, compositions, and therapeutic methods instead of using a COX-2 inhibitor other than celecoxib or valdecoxib.

One of ordinary skill in the art would have been motivated to combine the teachings of the two references in order to treat diseases, such as osteoarthritis, that are caused by unbalanced MMP activity, while simultaneously treating the pain and inflammation caused by such conditions. One of ordinary skill in the art would have reasonably expected success because '663 already teaches a combination of a COX-2 inhibitor and an allosteric MMP-13 inhibitor, and because valdecoxib was already known to be a therapeutically effective COX-2 inhibitor for the treatment of arthritis and related

Art Unit: 1623

conditions. The claimed invention of instant claims 3-9 is an obvious subspecie of this variation of the invention of claims 1 and 4-9 of '663, and is thus obvious over '663 in view of Goldman et al.

This is a provisional obviousness-type double patenting rejection as the conflicting claims have not in fact been patented.

Summary

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Olson

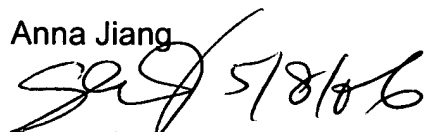
A handwritten signature in black ink, appearing to read "Eric S. Olson", written over the printed name.

Patent Examiner

AU 1623

5/5/2006

Anna Jiang

A handwritten signature in black ink, appearing to read "Anna Jiang", written over the printed name.

Supervisory Patent Examiner

AU 1623